UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

STEUBEN FOODS, INC.,

Plaintiff,

v.

Civil Action No.
1:13-cv-892-EAW-JJM

NESTLÉ USA, INC.

Defendant.

REPLY BRIEF OF NESTLÉ USA, INC., IN SUPPORT OF DEFENDANTS' JOINT MOTION FOR PARTIAL SUMMARY JUDGMENT FOR LACK OF WRITTEN DESCRIPTION AND THE COURT'S RULE 56(F) NOTICE

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I. Introduction

Steuben's patents lack written description for a process that meets the 1999 FDA standards for "aseptically disinfecting" using an oxonia sterilant. *See generally* Dkt. 336 [Defs. Mem.].[1] This lack of written description leaves the Court with two options:

> **Option 1**. Construe "aseptically disinfecting" to encompass the use of oxonia, which renders *all* claims invalid for lack of written description.
>
> **Option 2**. Construe "aseptically disinfecting" as limited to processes using hydrogen peroxide, preserving the validity of each claim that does not specifically require oxonia (i.e., only asserted claim 40 is invalid).

See Dkt. 336 [Defs. Mem.] at 19.

The Federal Circuit provides clear guidance to courts facing such a dilemma. "If, after applying all other available tools of claim construction, a claim is ambiguous, it should be construed to preserve its validity." *Ruckus Wireless, Inc. v. Innovative Wireless Solutions, LLC*, 824 F.3d 999, 1004 (Fed. Cir. 2016) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1327 (Fed. Cir. 2005)); *see also Medtronic Navigation, Inc. v. BrainLab Medizinische Computersysteme GmbH*, 222 Fed. App'x 952, 956 (Fed. Cir. 2007) (affirming construction that excluded system mentioned in the specification without a description of its use). The law, therefore, favors **Option 2**—construe "aseptically disinfecting" to cover only hydrogen peroxide and find claim 40 invalid.

Faced with the prospect of losing all its "aseptically disinfecting" claims, Steuben requests **Option 2**. Specifically, Steuben cites *Medtronic* and suggests that "it would be appropriate to narrow the construction of 'aseptically disinfecting' to include only the use of

[1] Docket entries are made to *Steuben Foods, Inc. v. Nestlé USA, Inc.*, No. 1:13-cv-892-EAW-JJM, unless otherwise noted.

hydrogen peroxide." Dkt. 351 [Opp.] at 34. NUSA agrees, as Defendants[2] previously proposed. Dkt. 336 [Defs. Mem.] at 19-25.

II. Defendants have demonstrated that "aseptically disinfecting" excludes oxonia

Defendants long have argued that "aseptically disinfecting" must be limited to processes using hydrogen peroxide. In its *Markman* submissions and Memorandum, for example, NUSA presented the following arguments and evidence, among others, in support of that construction.

- Specification. Steuben's patents define "aseptic"[3] as the "FDA level of aseptic," and instruct that the "aseptic filler must . . . use an FDA (Food and Drug Administration) approved sterilant." '013 patent, 1:48-50; *see* Dkt. 272 at 14.

- Prosecution History. Steuben repeatedly confirmed to the Patent Office that the claims require using an "FDA-approved sterilant" *See* Dkt. 272 at 14-16. Steuben distinguished prior art that used non-FDA-approved sterilants, arguing that "the only FDA approved sterilant for use in low acid packaging [in 1999] was hydrogen peroxide, [and] as such chlorine could not have been used in [an] aseptic packaging system as claimed." *Id.* at 15-16. Steuben and its experts also specifically distinguished prior art that used oxonia, on the basis that oxonia did not qualify as an FDA-approved sterilant. *Id.* at 16.

- Extrinsic Evidence. NUSA's experts and contemporaneous publications confirm that, in 1999, hydrogen peroxide was the only FDA-approved sterilant. *Id.* at 16-17. The inventor further admitted that he did not perform tests using oxonia, and that someone would have to develop the oxonia process, research the efficacy of oxonia, prepare test data, present it to the FDA, and then the system "*might* have been approved" by the FDA, but that was not certain. Dkt. 336 [Defs. Mem.] at 11 (emphasis added).

For the reasons set forth in the briefing, any ambiguity between Steuben's patents defining "aseptic" in a manner that *excludes* oxonia and the specification's passing reference to oxonia is resolved by Steuben's prosecution disclaimers and the extrinsic evidence: oxonia is *not* part of the claimed invention. *See, e.g.*, Dkt. 272 at 22 § I.A.3.d. The Court's progression of

[2] NUSA, GEA, and Jasper moved jointly for summary judgment and are referred to herein collectively as the "Defendants."

[3] The parties agree that this definition applies to "aseptically disinfecting."

claim construction orders and Rule 56 notices, however, suggests that, at least in the Court's view, some ambiguity remains. In that event, *Medtronic* applies and "aseptically disinfecting" should be construed to exclude oxonia to preserve claim validity.

III. Construing "aseptically disinfecting" to exclude oxonia would return the Court to its initial, proper construction

When the Court provided its initial, tentative construction of "aseptically disinfecting," it limited the term to hydrogen peroxide processes, in part because Steuben's claims cannot validly encompass oxonia. *See* Dkt. 318 (Feb. 13, 2018). In subsequent rulings, the Court's construction shifted to one broad enough to cover oxonia—a construction fatal to the claims' validity. *See* Dkt. 330. Construing "aseptically disinfecting" to preserve the claims' validity—as the Defendants and now Steuben propose—would return the Court to its initial, correct construction.

A. The First Rule 56(f)(3) Notice properly construed "aseptically disinfecting" in view of the inadequate disclosure of an oxonia invention

In its First Rule 56(f)(3) Notice, the Court indicated its intention to consider as part of its claim construction (1) the patents' insufficient disclosure of oxonia processes and (2) the resulting invalidity of Claim 40 of the '188 patent. *See* Dkt. 318. In that Notice, the Court found undisputed the facts that (1) "the 'aseptically disinfecting' method of the Steuben patents requires the use of an 'FDA approved sterilant'" and (2) in 1999, "the only FDA approved sterilant for use in low acid packaging was hydrogen peroxide." *Id.* at 2-3. The Court questioned Steuben's argument that "oxonia . . . can be used to practice the claimed invention," because Steuben's patent disclosure did not appear to support such claim scope. *Id.* at 3.

The First Rule 56(f)(3) Notice focused on lack of enablement (35 U.S.C. § 112) and utility (§ 101), whereas the Court is now considering the patents' lack of written description (§ 112) for oxonia. These validity concerns, however, are analogous in their claim construction

implications. The First Rule 56(f)(3) Notice also acknowledged the tension created by claim 40 of the '188 patent, which excludes oxonia (by reciting a process for "aseptically disinfecting") *but also* recites using oxonia. *Id.* at 5. To resolve that ambiguity, the Court proposed to save Steuben's remaining patent claims at the expense of claim 40 by invalidating claim 40 and "limiting the meaning of the phrase 'aseptically disinfecting' as used in the other patent claims to those methods using hydrogen peroxide as the sterilant." *Id.* at 6.

B. The Second Rule 56(f)(3) Notice shifted toward construing "aseptically disinfecting" in a manner that invalidates the claims

Steuben opposed the First Rule 56(f)(3) Notice, urging the Court to adopt a broader construction of "aseptically disinfecting," not limited to hydrogen peroxide. Dkt. 322. Steuben argued that the Court should adopt the Federal Circuit's construction of "aseptically disinfecting"[4] and that "the Court need not, and should not, consider validity in order to assign a different construction of the claim term 'aseptically disinfecting.'" *Id.*

In an apparent effort to accommodate Steuben's opposition, the Court issued a Second Rule 56(f)(3) Notice on April 3, 2018. Dkt. 326.[5] The Court shifted its focus from the patent's deficient disclosure to its conclusion that "it appears to me that 'the use of oxonia, regardless of whether it was described, was not invented' by Taggart." Dkt. 326 at 1. The Court tentatively concluded that "even if the phrase 'aseptically disinfecting' can be construed to include oxonia

[4] The Federal Circuit's construction alone, is insufficient to resolve the questions pending before this Court. *See* Dkt. 292 at 2-3. Construing "aseptically disinfecting" to exclude oxonia would not be inconsistent with the Federal Circuit's construction to meet the "FDA level of aseptic" in 1999, because that construction requires an "FDA approved sterilant" (i.e., using hydrogen peroxide), as explained in NUSA's Markman submissions. Dkt. 292 at 1-3.

[5] At that time, the Court did not have Steuben's current proposal—that it *should* consider validity when determining the construction and *should* construe the claims to preserve their validity—which is the opposite of what it proposed in in response to the First Rule 56(f)(3) Notice.

as the sterilant, the patents cannot validly be applied to encompass its use." *Id.* at 5. In short, in its Second Rule 56(f)(3) Notice the Court shifted toward construing "aseptically disinfecting" in a manner that would invalidate *all* of Steuben's patent claims.

C. The April 20 Decision and Order construed "aseptically disinfecting" in a way that invalidates all of Steuben's claims

On April 20, 2018, the Court confirmed this shift. In a Decision and Order (D&O), the Court acknowledged its previous view that "the phrase 'aseptically disinfecting' as used in the patents precluded the use of oxonia as the sterilant." Dkt. 330 at 2. "However," the Court explained, it "no longer [held] that view." *Id.* Rather than invalidate claim 40 as inconsistent with a construction of "aseptically disinfecting" that excluded oxonia, the Court determined that claim 40 mandated construing the term broadly enough to reach that sterilant. *Id.* at 2-3.

To support this new approach, the Court changed its interpretation of the patents' requirement that the "aseptic filler must . . . use an FDA . . . approved sterilant." *Id.* at 4-5; '013 patent, 1:48-50. The Court previously viewed that statement as limiting the claims to hydrogen peroxide (the only FDA approved sterilant in 1999). In the D&O, however, the Court endorsed Steuben's "attempt to substitute the word 'approvable' for 'approved'" in the specification. *Id.* at 4. In effect, rather than construe "aseptically disinfecting" in view of the patent's lexicography, the Court deemed it more appropriate to modify the lexicography to fit Steuben's new construction, despite Steuben's failure to cite any authority to support rewriting the language of the specification. Nor did the Court explain why this modification was proper in view of the contrary authority the Court recognized by its First Rule 56(f)(3) Notice:

> Having used the word "approved" rather than "approvable" in the specification, the inventor "must live with the language it chose." Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1583 (Fed. Cir. 1996); SSIH Equipment S.A. v. U.S. International Trade Commission, 718 F.2d 365, 386 (Fed. Cir. 1983) ("a patentee is bound by his specification in

> interpreting his patent claims even when his specification requires a narrower interpretation of the claims than the patentee desires").

Dkt. 318 [First Rule 56(f)(3) Notice] at 2 n.2.

NUSA respectfully submits that the Court's changed construction—from the First Rule 56(f)(3) Notice to the April 20 D&O—was incorrect. Claim 40's recitation of oxonia does *not* require construing "aseptically disinfecting" to encompass it. *See* Dkt. 336 [Defs. Mem.]at 23-25; Dkt. 292 at 12, 14. Steuben implicitly acknowledges this by proposing that "aseptically disinfecting" *can* be (and *should* be) construed to exclude oxonia if the broader construction would render the claims invalid. Dkt. 351 at 34. Moreover, as Defendants explained in their Memorandum, it is appropriate to find claim 40 *invalid* when the proper construction of one claim term ("aseptically disinfecting") is inconsistent with another claim term ("peroxyacetic acid"/oxonia).[6] *See* Dkt. 336 at 23-25. The Federal Circuit itself has construed claims in a way that is "nonsensical in the way a claim to extracting orange juice from apples would be," holding such claim invalid as "indefinite." *See, e.g., Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1366-67 (Fed. Cir. 2016); *Cave Consulting Group v. OptumInsight, Inc.*, 725 F. App'x 988, 995 (Fed. Cir. 2018) (nonprecedential). Thus, the law does not require changing the meaning of a claim term that is apparent from the intrinsic record—as here to exclude oxonia—to accommodate a claim that uses the term in an inconsistent manner.

IV. The Court should construe "aseptically disinfecting" to exclude oxonia sterilants because the patents lack written description, as Steuben requests

NUSA maintains—as set forth in its *Markman* briefing (Dkts. 272, 292)—that the specification, prosecution history, and other evidence conclusively establish that "aseptically

[6] If the Court limits the construction of "aseptically disinfecting" to the use of hydrogen peroxide systems, Defendants request that the Court simultaneously enter judgment that claim 40 is invalid, consistent with the Court's First Rule 56(f) Notice, or allow Defendants to so move.

disinfecting" cannot cover oxonia. Nonetheless, the Court's struggle regarding whether "aseptically disinfecting" requires an "approved" sterilant or one "capable of being approved" in 1999, suggests the Court may perceive an ambiguity in whether oxonia sterilants fall within the scope of "aseptic."[7] Such an ambiguity would align this case squarely with *Medtronic* and inform the proper construction. In *Medtronic*, the claims generically recited a tracking system, but the patent disclosure focused on a single "acoustic tracking system" embodiment. *Medtronic*, 222 Fed. App'x at 956. The disclosure also referred superficially to an "optical tracking system," but provided no enabling written description of an invention using such a system. *Id.* The Federal Circuit construed the claims to exclude the "optical tracking system," explaining that:

> Because this case is one in which ambiguity as to the scope of the claim language can be "resolved in a manner that would preserve the patent's validity," that principle can properly be applied here.

Id. (internal citation omitted) (quoting *Phillips*, 415 F.3d at 1327). In reaching this decision, the Federal Circuit noted that the inventor admitted that he *did not* possess an invention that used an "optical tracking system" at the patent's filing, and it was simply disclosed in the patent specification because "[i]t seemed at the time that this would be an obvious development, that it would be coming in time." *Id.* Based on the specification's lack of disclosure and the inventor's admission, the Federal Circuit concluded that "rather than being a disclosure of an optical system sufficient to support an interpretation of a claim as including an optical system, it was merely 'an attempt to preempt the future before it has arrived,'" and the court construed the claims to exclude optical tracking systems. *Id.* at 956-57.

Here, as in *Medtronic*, Steuben's patents describe only one aseptic system, and that

[7] NUSA believes the prosecution history shows Steuben's position, which acts as disclaimer and limits the scope of the claims, that oxonia was *not capable* of being approved in 1999.

system uses hydrogen peroxide as a sterilant. Dkt. 336 [Defs. Mem.] at 8-9. Further, the specification states that an aseptic filler must "use an FDA . . . approved sterilant," which in 1999 meant *only* hydrogen peroxide. '013 patent, 1:48-50. On the other hand, the patent specification mentions using oxonia as an aseptic sterilant (without describing a process to achieve FDA aseptic disinfection using it), and '188 patent claim 40 specifically recites oxonia.[8]

As in *Medtronic*, one construction of "aseptically disinfecting" would render all claims invalid for lack of written description, while the other construction "would preserve the patent's validity" (except for indefinite claim 40). Under *Medtronic*, ambiguities in claim scope allow the Court to apply the narrower construction and preserve the validity of all but one of Steuben's "aseptically disinfecting" claims. Moreover, just as in *Medtronic*, the inventor's testimony confirms the proper construction. Mr. Taggart admitted that he never tested oxonia, and that someone would have to develop the oxonia process, research the efficacy of oxonia, prepare test data, present it to the FDA, and then the system "might have been approved" by the FDA, but that was not certain—i.e., he did *not* invent an oxonia process. Dkt. 272-15, Ex. N14, Taggart Dep. Tr. 388:3-16. As a result, Steuben's patent's "minimal dropping of an unenabled reference to an undeveloped [oxonia] system does not support a claim to it," and "was merely 'an attempt to preempt the future before it has arrived,'" making it proper to exclude oxonia from the scope of the claims. *Medtronic*, 222 Fed. App'x at 957.

[8] Claim 40 was added to the '188 patent during reexamination to cover the oxonia machines accused of infringement after Steuben sued GEA. This added claim cannot be used to broaden the scope of "aseptic." *Total Containment, Inc. v. Environ Prods., Inc.*, 106 F.3d 427, at *2 (Fed. Cir. 1997) (nonprecedential)

V. Conclusion

For the foregoing reasons and the reasons set forth in the Defendants' Memorandum, NUSA agrees with Steuben's proposal to limit the construction of "aseptically disinfecting" to processes using hydrogen peroxide. This construction is consistent with the intrinsic record and confirmed by extrinsic evidence, as set forth in Defendants' *Markman* submissions. Moreover, this construction would avoid encompassing subject matter that would render all of Steuben's "aseptic" claims invalid for lack of written description.

Dated: September 14, 2018

By: /s/ Virginia L. Carron

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CERTIFICATE OF SERVICE

I hereby certify that on September 14, 2018, I electronically filed the **REPLY BRIEF OF NESTLÉ USA, INC., IN SUPPORT OF DEFENDANTS' JOINT MOTION FOR PARTIAL SUMMARY JUDGMENT FOR LACK OF WRITTEN DESCRIPTION AND THE COURT'S RULE 56(F) NOTICE** with the Clerk of the District Court using the CM/ECF system, which sent notice to the counsel of record.

/s/ Virginia L. Carron